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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,995	01/15/2002	Robert DeLeys	2752-58	1876

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EXAMINER	
WORTMAN, DONNA C	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 03/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/044,995	DELEYS ET AL.	
	Examiner	Art Unit	
	Donna C. Wortman, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *27,28,30,34,35,37,41,42,44,48,49 and 51* is/are allowed.

6)☒ Claim(s) *26,29,31-33,36,38,39,40,43,45-47,50, 52-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 07/920,286.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.

Claims 26, 29, 31, and 32 were amended and claims 54-59 were added in the response filed 30 December 2003. Claims 26-59 are pending. Claims 27, 28, 30, 34, 35, 37, 41, 42, 44, 48, 49, and 51 were previously indicated as allowed.

Objection, necessitated by amendment

Claim 56 is objected to because of the following informalities: Claim 56, line 1, should have a comma after "6", so that it would read: "A peptide consisting of 5, 6, 8, 12 or 20 amino acids ...". Appropriate correction is required.

Rejections, necessitated by amendment

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 54 is rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 388 232 to Houghton et al., published 9/1990, of record. Houghton discloses amino acid sequences that can be prepared as peptides comprising HCV epitopes that correspond to 6 amino acids of amino acids 1-20 of the HCV polyprotein of an HCV isolate, namely AA20-AA25 (see page 15, line 32). Also see Fig. 17-1 for amino acid sequence corresponding to the peptides.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 58 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 388 232 to Houghton et al. as cited above and applied to claim 54. Houghton teaches that the disclosed peptides containing HCV epitopes are suitable for including in compositions such as kits for immunoassays. The claimed kits and methods would have been obvious to one of ordinary skill in the art at the time the invention was made over the cited teachings of EP 0 388 232.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 47, 50, 52, and 53 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 4, 6, and 7, respectively, of prior U.S. Patent No. 6,007,982. This is a double patenting rejection.

Claim 47 is drawn to a peptide consisting of amino acids 1 to 20 of the HCV polyprotein of an HCV isolate which is capable of providing for immunological competition with at least one strain of HCV wherein said amino acids 1 to 20 are SEQ ID NO:1. Claim 1 of Patent 6,007,982 is drawn to an isolated peptide having the amino acid sequence shown in SEQ ID NO:1. While the claims are not identically worded, both claims are interpreted as being drawn to identical subject matter, *viz.*, a peptide consisting of the amino acid sequence of SEQ ID NO:1, since the instant specification discloses synthetic, i.e., isolated, peptide consisting of SEQ ID NO:1, and since "having the amino acid sequence" in claim 1 is interpreted as being closed language, equivalent to "consisting of the amino acid sequence." Similarly, claim 50 and patent claim 4; claim 52 and patent claim 6; and claim 53 and patent claim 7 are interpreted as being drawn to identical subject matter. If the claims are amended or if it is established on this record that the instant claims 47, 50, 52, and 53 are not of the same scope as the corresponding patent claims, they are likely to be subject to nonstatutory double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 26, 29, 31, 32, 33, 36, 38, 39, 40, 43, 45, 46, and 54-59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 6, 7 and 15-21 of U.S. Patent No. 6,007,982. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the same subject matter, differing only in scope such that claims 26, 29, 31-33, 36, 38-40, 43, 45, and 46 fully encompass the subject matter of patent claims 1, 4, 6, 7, and 15-21. Claims 54-59, insofar as drawn to a peptide consisting of 20 amino acids, also encompass the subject matter of claims 1, 4, 6, 7 and 15-21.

Rejections withdrawn

The rejection of claims 26, 47, 29, 50, 31, 52, 32 and 53 under 35 U.S.C. 102(b) and the rejection of claims 33, 40, 36, 43, 38, 45, 39 and 46 under 35 U.S.C.103(a), both over EP 0 388 232 to Houghton et al., are withdrawn in view of Applicant's amendments to claims 26, 29, 31, and 32.

Applicant's remarks and Annex 1 have also been noted.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 571-272-0913. Until 31 March 2004, the examiner can normally be reached on Monday-Thursday, 7:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Donna C. Wortman, Ph.D.
Primary Examiner
Art Unit 1648

dcw